UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF ILLINOIS

IN RE YASMIN AND YAZ (DROSPIRENONE) MARKETING, SALES PRACTICES AND RELEVANT PRODUCTS LIABILITY LITIGATION	**3:09-MD-02100-DRH-CJP** **MDL No. 2100** **Judge David R. Herndon**
RHONDA PETERSON, an individual, ***Plaintiffs,*** **v.**	**Civil Action No.: 3:14-cv-10252-DRH-PMF**
BAYER CORPORATION; BAYER HEALTHCARE, LLC; BAYER PHARMACEUTICALS CORPORATION; BAYER HEALTHCARE PHARMACEUTICALS, INC.; BERLEX LABORATORIES, INC., BERLEX, INC.; BAYER PHARMA AG; BAYER AG; BARR LABORATORIES, INC.; BARR PHARMACEUTICALS, LLC; BARR PHARMACEUTICALS, INC.; TEVA PHARMACEUTICALS; and, TEVA USA, ***Defendants.***	**COMPLAINT AND JURY DEMAND**

COMPLAINT

COMES NOW the above-named Plaintiff, by and through the undersigned counsel of record, to file this complaint for damages. As grounds, Plaintiff alleges and states as follows:

PARTIES AND JURISDICTION

1. Plaintiff RHONDA PETERSON (hereinafter "Plaintiff") is an adult resident citizen of the State of Minnesota and currently resides in Fridley, Minnesota. At all material

times, Plaintiff was and is a resident of Anoka County, Minnesota. Plaintiff was prescribed and ingested Yaz, Yasmin and/or Ocella and suffered injury, including, but not limited to pulmonary embolism, deep vein thrombosis and the associated conditions related thereto.

2. Defendant Bayer Corporation is a foreign corporation existing and doing business pursuant to the laws of the state of Indiana and with its principal place of business at 100 Bayer Road, Building 4, Pittsburgh, Pennsylvania 15205. At all times material and relevant, Bayer Corporation conducts business throughout the United States, including the state of Minnesota, directly and indirectly through its agents and distributors to such an extent that it avails itself of the jurisdiction of this court.

3. Defendant Bayer Healthcare, LLC is a Delaware limited liability company, with its principal place of business at 555 White Plains Road, Tarrytown, New York 10591. Bayer Healthcare, LLC was involved in the integration of Bayer Healthcare and Berlex Laboratories. Defendant Bayer Healthcare, LLC is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Yaz, Yasmin, and Ocella. At all relevant times, Bayer Healthcare, LLC conducted and sustained regular business in Minnesota by selling and distributing its products in Minnesota and engaged in substantial commerce and business activity in Georgia.

4. Defendant Bayer Healthcare, LLC is wholly owned by Defendant Bayer Corporation.

5. Defendant Bayer Pharmaceuticals Corporation is, and at times relevant was a corporation organized under the laws of the State of Delaware with its headquarters and principal place of business at 1400 Morgan Lane, West Haven, Connecticut.

6. Defendant Bayer Corporation is the sole member of Bayer Healthcare, LLC, which owns 100% of Schering Berlin, Inc., which owns 100% of Defendant Bayer Healthcare

Pharmaceuticals, Inc. As such, Defendant Bayer Corporation is a parent of Defendant Bayer Healthcare Pharmaceuticals, Inc.

7. Defendant, Bayer Healthcare Pharmaceuticals, Inc. is a Delaware corporation with its principal place of business at 6 West Belt Road, Wayne, New Jersey, 07470. Bayer Healthcare Pharmaceuticals, Inc. was created by the integration of Bayer Healthcare and Berlex Laboratories. Defendant Bayer Healthcare Pharmaceuticals, Inc. is the U.S. based pharmaceuticals unit of Schering Berlin, Inc. and is a division of Bayer AG.

8. As of January 1, 2008, Defendant Bayer Pharmaceuticals Corporation was merged into Defendant Bayer Healthcare Pharmaceuticals, Inc.

9. At all relevant times, Defendant Bayer Corporation was engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Yaz, Yasmin, and Ocella. At all relevant times, Defendant Bayer Corporation conducted and sustained regular business in Georgia by selling and distributing its products in Minnesota and engaged in substantial commerce and business activity in Minnesota.

10. Defendant Bayer Healthcare Pharmaceuticals, Inc. is a corporate successor to Berlex Laboratories, Inc. (Berlex), which was formerly known as Berlex, Inc., and as such is obligated for its predecessor's liabilities. Berlex was formally engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling directly and indirectly through third parties or related entities, the drug Yaz, Yasmin, and Ocella.

11. Berlex Laboratories International, Inc. was engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Yaz, Yasmin, and Ocella. At all relevant times, Berlex Laboratories International, Inc. conducted and sustained regular business

in Minnesota by selling and distributing its products in Minnesota and engaged in substantial commerce and business activity in Minnesota.

12. Berlex Laboratories International, Inc. was a Delaware corporation with its principal place of business in Montville, New Jersey. Berlex Laboratories International, Inc. was integrated with Bayer Healthcare, leading to the creation of Bayer Healthcare Pharmaceuticals, Inc. As such, Defendant Bayer Healthcare Pharmaceuticals, Inc. is liable for the actions and omissions of Berlex laboratories International, Inc.

13. Defendant Bayer Healthcare Pharmaceuticals, Inc. was the holder of the approved New Drug Application ("NDA") for Yaz®.

14. Defendant Bayer Healthcare Pharmaceuticals, Inc. was also the holder of the approved NDA for Yasmin®.

15. Defendant Bayer Pharma AG, formerly known as Bayer Schering Pharma AG, and also formerly known as Schering AG, is a pharmaceutical company that is organized and existing under the laws of the Federal Republic of Germany, having a principal place of business at Müllerstrasse 178, 13353 Berlin, Germany.

16. Defendant Bayer Pharma AG is a corporate successor of Bayer Schering Pharma AG and Schering AG.

17. Schering AG was renamed Bayer Schering Pharma AG effective December 29, 2006.

18. Bayer Schering Pharma AG was renamed Bayer Pharma AG effective July 5, 2011.

19. Defendant Bayer Pharma AG's headquarters and principal place of business in the United States is located at 100 Bayer Road, Pittsburgh, Pennsylvania 15205.

20. Defendant Bayer Pharma AG is the current owner of the patent(s) relating to the oral contraceptive, Yasmin®.

21. Defendant Bayer AG is a German chemical and pharmaceutical company that is headquartered in Leverkusen North Rhine-Westphalia, Germany.

22. Defendant Bayer AG is the parent/holding company of all other named Bayer-related entitled named herein as defendants.

23. Defendant Bayer AG's headquarters and principal place of business in the United States is located at 100 Bayer Road, Pittsburgh, Pennsylvania, 15205.

24. Defendants Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare, LLC, Bayer Pharma AG and Bayer AG, are collectively referred to herein as "Bayer," "Bayer Defendants," or "Defendants."

25. Defendant McKesson Corporation is a Delaware limited liability company, with its principal place of business at One Post Street, San Francisco, California 94104. Defendant McKesson Corporation packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted and purported to warn or to inform users regarding the risks pertaining to, assuaged concerns about the pharmaceutical, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its precuts, including the prescription drug Yaz, Yasmin, and Ocella.

26. Defendant Barr Laboratories, Inc. ("BLI") is and at all times relevant was a corporation organized under the laws of the state of Delaware having regular and established places of business at One Belmont Avenue, Bala Cynwyd, Pennsylvania and 255 Summit Avenue, Montvale, New Jersey.

27. Defendant Barr Pharmaceuticals, LLC, formally known as Barr Pharmaceuticals, Inc. ("BPI") is an at all relevant times was a corporation organized under the laws of the state of Delaware having regular and established places of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey 07677; 109 Morgan Lane, Plainsboro, New Jersey 08536; and, 264 Livingston Street, Northvale, New Jersey 07647 with its principal place of business in Woodcliff Lake, New Jersey.

28. BLI is or was a wholly-owned subsidiary of BPI.

29. Defendants BLI and BPI shall be referred to herein individually by name or collectively as "Barr" and/or the "Barr Defendants" or collectively with all Defendants as "Defendants."

30. Defendant Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") is and at all times relevant was a pharmaceutical corporation organized under the laws of Israel and maintains its principal place of business at 5 Basel Street, Petah Tiqva 49131, Israel.

31. Defendant Teva USA is an indirect wholly-owned subsidiary of Teva Ltd.

32. Defendants Teva Ltd. and Teva USA shall be referred to herein individually by name or collectively as "Teva" and/or the "Teva Defendants" or collectively with all Defendants as "Defendants."

33. Teva is among the top 20 pharmaceutical companies and among the largest generic pharmaceutical companies in the world.

34. This court has jurisdiction over this action pursuant to 28 U.S.C. §1332 because there is complete diversity of citizenship between the parties, and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

35. This Court has personal jurisdiction over Defendants consistent with the United States Constitution and MDL No. 2100 as Plaintiff's claims arise out of Defendants' transaction of business and the commission of tortious acts within the State of Minnesota, and by virtue of Defendants' substantial, continuous, and systematic contacts with the State of Minnesota. Any contacts by Defendants with the State of Illinois are unrelated to Plaintiff's claims.

VENUE

36. Venue in this district is appropriate under 28 U.S.C. §1391(a) and (c) because Defendants are subject to personal jurisdiction in this venue. Furthermore, Plaintiff is filing this Complaint as permitted by Case Management Order No. 9 issued by Judge David R. Herndon of this Court. Plaintiff states that, but for Order No. 9 permitting direct filing into the Southern District of Illinois, Plaintiff would have filed in the United States District Court for the District of Minnesota, which is where Plaintiff lived at the time that she used the product at issue and

suffered the injuries alleged in this Complaint. Therefore, Plaintiff respectfully requests that at the time of transfer of this action back to the trial court for further proceedings, this case be transferred to the United States District Court of Minnesota of as set forth in Case Management Order No. 9.

FACTUAL BACKGROUND

I. Nature of the Case

37. Plaintiff brings this case against Defendants for damages associated with her ingestion of the pharmaceutical drug Yaz, Yasmin, and/or Ocella (ethinyl estradiol and drospirenone), which are oral contraceptives designed, manufactured, supplied, marketed, and distributed by Defendants. As a direct result of her use of Yaz, Yasmin, and Ocella/Ocella, Plaintiff suffered a pulmonary embolism and deep vein thrombosis.

II. Bayer's Combined Oral Contraceptives – Yaz & Yasmin

38. Yaz®, Yasmin®, and Ocella® are pills manufactured and marketed by Defendants to treat menometrorrhagi and as a form of birth control. They are combination oral contraceptives, or "COCs," meaning that they contain an estrogen component and a progestin component. Together, these steroidal components work together in COCs to suppress ovulation, fertilization, and implantation and thus prevent pregnancy.

39. Yaz® and Yasmin® were approved by the Food and Drug Administration for marketing in 2006 and 2001, respectively.

III. Yaz and Yasmin contain a "Fourth Generation" Progestin

40. The estrogen component in Yaz and Yasmin is known generically as ethinyl estradiol. The progestin component is known as drospirenone. Yasmin contains 0.03 milligrams of ethinyl estradiol, and Yaz contains 0.02 milligrams of ethinyl estradiol. Both products contain 3 milligrams of drospirenone.

41. Yaz and Yasmin are different from other combined hormonal birth control pills in that they contain drospirenone, a progestin that is unlike other progestins available in the United States and was never before marketed in the United States prior to its use in Yasmin.

42. Shortly after the introduction of combined oral contraceptives in the 1960's, doctors and researchers found that women using birth control pills had a high risk of blood clots, heart attacks, and strokes than women not using the pill. As a result, the various brands of birth control pills were reformulated to reduce the amounts of estrogen. As the amounts of estrogen levels reduced, so too did the risk of blood clots, heart attacks, and strokes.

43. During this time, new progestins were being developed, which became known as "second generation" progestins (e.g. lovenorgestrel). These second generation progestins, which combined with the lower amounts of the estrogen, ethinyl estradiol, helped to reduce the risk of blood clots, heart attacks, and strokes and were considered safer for women.

44. During the 1990's, new "third generation" progestins were developed. Unfortunately, these "third generation" progestins (e.g., gesodene and desogestrel) have been associated with a greater risk of blood clots in the deep veins (deep vein thrombosis or "DVT") and lungs (pulmonary embolism or "PE"). As a result of this increased risk of blood clots, the FDA has required that products containing third generation progestins include a warning of the potentially increased risk of thrombosis.

45. Yaz, Yasmin, and Ocella contain the same estrogen component, ethinyl estradiol, which has been used in the lower dose birth control pills for decades.

46. However, drospirenone is a new type of progestin and is considered a "fourth generation" progestin. No other birth control pills contain drospirenone.

47. Since drospirenone is new, there is insufficient data available to support its safe use, particularly compared with second generation progestins. In fact, studies performed prior to FDA approval indicate that drospirenone has certain effects that are different from those of traditional second generation progestins, and potentially more dangerous.

48. One possible mechanism of action is that drospirenone causes an increase in potassium levels in the blood, which can lead to a condition known as hyperkalemia if the potassium levels become too high. Hyperkalemia can cause heart rhythm disturbances, such as extrasystolies, pauses, or bradycardia. If left untreated, hyperkalemia can be fatal. If hyperkalemia disrupts the normal heart rhythms, the flow of blood through the heart can be slowed to the point that it permits blood clots to form. Blood clots in the heart can then lead to heart attacks, or the clots can break off and travel to the lungs where they can cause pulmonary embolism, or can travel to the brain causing stroke.

49. During the brief time that Yaz and Yasmin have been sold in the United States, hundreds of reports of injury and death have been submitted to the FDA in association with Defendants' products.

50. In April of 2002, the British Medical Journal reported that the Dutch College of General Practitioners recommended that older second generation birth control pills should be prescribed in lieu of Yasmin as a result of 40 cases of venous thrombosis among women taking Yasmin.

51. In February of 2003, a paper entitled *Thromboembolism Associated with the New Contraceptive Yasmin* was published in the British Medical Journal detailing a Netherlands Pharmacovigilance Centre report of five additional reports of thromboembolism where Yasmin was suspected as the cause, including two deaths.

52. In fact, in less than a five-year period, from the first quarter of 2004 through the third quarter of 2008, over 50 reports of death among users of Yaz, Yasmin and/or Ocella have been filed with the FDA. These reports include deaths associated with cardiac arrhythmia, cardiac arrest, intracardiac thrombus, pulmonary embolism, and stroke in women in their child bearing years.

53. One of the deaths reported to the FDA occurred in a woman 17 years old.

54. Significantly, reports of elevated potassium levels are frequently included among the symptoms of those suffering death while using Yaz, Yasmin and/or Ocella.

55. Two recent studies, released in August of 2009, have found significantly increased risks of harm associated with Yasmin or Yaz compared to other types of birth control pills. The first study assessed the risk of developing venous thrombosis in women who use oral contraception. The women ranged in age from 15 to 49 and had no history of heart disease or any malignant condition. The study found that of the 3.3 million women taking oral contraceptives, there were 4,213 venous thrombotic events. Of this total, 2,045 occurred in women using drospirenone oral contraceptives. The study concluded "oral contraceptives with … drospirenone were associated with a significantly higher risk of venous thrombosis than other oral contraceptives with levonorgestrel." Lidegard, et al., *Hormonal contraception and risk of venous thromboembolism; national follow up study*, THE BRITISH MEDICAL JOURNAL 2009, 330; B2921.

IV. Over-Promotion of Yaz, Yasmin, and Ocella

56. Defendants marketed Yaz, Yasmin, and Ocella as providing the same efficacy as other birth control pills in preventing pregnancy, but with additional benefits.

57. However, because Yaz, Yasmin, and Ocella contain the fourth generation progestin, drospirenone, each presents additional heath risks not associated with other birth control pills.

58. For example, prior to its sale to Defendant Bayer in 2006, Berlex Laboratories promoted Yasmin's fourth generation progestin, drospirenone, by stating, "Ask about Yasmin, and the difference a little chemistry can make."

59. In response, on July 10, 2003, the FDA objected to the characterization that drospirenone was a benefit compared to the progestin used in other combined oral contraceptives, and issued a warning letter stating, "FDA is not aware of substantial evidence of substantial clinical experience demonstrating that Yasmin is superior to other COCs or that the drospirenone in Yasmin is clinically beneficial. On the contrary, FDA is aware of the added clinical risks associated with drospirenone[.]"

60. The FDA's warning letter continued by stating that the advertisement failed "to communicate that the potential to increase potassium is a risk" or that "increased serum potassium can be dangerous."

61. More recently, Defendants advertised that its product (Yaz, Yasmin, and Ocella) was indicated for treatment of premenstrual syndrome or "PMS," as opposed to the less serious condition of premenstrual dysphoric disorder or "PMDD."

62. Defendants also advertised that its product (Yaz, Yasmin, and Ocella) contained the added benefit of preventing or reducing acne.

63. In response, on October 3, 2008, the FDA issued another warning letter to Defendant Bayer for the misleading advertisement, reiterating that the marketing was misleading because it promoted Yaz, Yasmin, and Ocella for medical conditions beyond the limits of the FDA approval, and adding that "Yaz has additional risks because it contains the progestin, drospirenone… which can lead to hyperkalemia in high risk patients, which may result in potentially serious heart and health problems."

64. The FDA further warned in its October 3, 2008 letter that Yaz "does not result in completely clear skin" and that Defendants' "TV ads misleadingly overstate the efficacy of the drug."

65. Indeed, the FDA felt that Defendants' over-promotion was so severe that it required Bayer to run new TV advertisements to correct the previous misleading Yaz advertisements regarding acne and premenstrual syndrome.

66. Defendant Bayer ultimately agreed to spend at least $20 million on corrective TV advertisements and to submit all Yaz, Yasmin, and Ocella/Ocella advertisements to the FDA for advanced screening for the next six years.

V. Plaintiff's Use of Yaz, Yasmin and Ocella and Resulting Injuries

67. As a result of Defendants' claims regarding the effectiveness, safety, and benefits of Yaz, Yasmin and/or Ocella, Plaintiff's doctor prescribed and Plaintiff ingested Yaz, Yasmin, and/or Ocella beginning on or about July 6, 2008.

68. As a direct and proximate result of continuous and/or repeated use of Yaz, Yasmin, and/or Ocella, Plaintiff suffered deep vein thrombosis and a pulmonary embolism.

69. As a direct and proximate result of continuous and/or repeated use of Yaz, Yasmin, and/or Ocella, Plaintiff suffered a pulmonary embolism and deep vein thrombosis requiring hospitalization and treatment.

70. Prior to Plaintiff's use of Yaz, Yasmin, and/or Ocella, Defendants knew or should have known that use of Yaz, Yasmin, and/or Ocella created a higher risk of pulmonary embolism than other oral contraceptives on the market, including but not limited to second generation oral contraceptives, and that, when taken as directed, such use was unreasonably dangerous to consumers.

71. Therefore, at the time Plaintiff used Yaz, Yasmin, and/or Ocella, Defendants knew or should have known that the use of Yaz, Yasmin, and Ocella created an increased risk to consumers of serious personal injury, including deep vein thrombosis, pulmonary embolism, heart attacks, stroke, gall bladder injuries, and even death.

72. Despite the fact that Defendants knew or should have known of the serious health risks associated with the use of Yaz, Yasmin and Ocella, Defendants failed to warn Plaintiff and/or her health care providers of said serious risks before she used the product.

73. Had Plaintiff and/or her health care providers known the risks and dangers associated with Yaz, Yasmin and Ocella, she would not have used Yaz, Yasmin, and/or Ocella and would not have suffered a pulmonary embolism or deep vein thrombosis.

74. As a direct and proximate result of her use of Yaz, Yasmin, and/or Ocella, Plaintiff suffered physical injury, including but not limited to, conscious pain and suffering, physical injury and bodily impairment, including but not limited to suffering from a pulmonary embolism and deep vein thrombosis that will affect her throughout her lifetime.

75. Further, as a direct and proximate result of her use of Yaz, Yasmin, and/or Ocella, Plaintiff has suffered significant mental anguish and emotional distress and will continue to

suffer physical limitations, pain, injury, damages, harm, and mental and emotional distress in the future.

76. Plaintiff has also incurred medical expenses and other economic harm and will continue to incur such expenses in the future, as a direct and proximate result of her use of Yaz, Yasmin, and/or Ocella.

COUNT I
PRODUCTS LIABILITY - DEFECTIVE DESIGN

77. Plaintiff incorporates by reference each preceeding and succeeding paragraph as though fully set forth herein.

78. Defendants designed the Yaz, Yasmin and Ocella in a defective manner which rendered the product unreasonably dangerous to the user or consumer.

79. Defendants knew or should have known about the danger that the Yaz, Yasmin, and Ocella posed to its users, including the Plaintiff.

80. The defective and unreasonably dangerous condition of the Yaz, Yasmin, and Ocella proximately caused the harm sustained by the Plaintiff.

81. Neither the Plaintiff nor her health care providers had knowledge that the Yaz, Yasmin, and Ocella was unsafe and they did not appreciate the danger in the defective condition of Yaz, Yasmin, and Ocella. Nor did the Plaintiff deliberately or voluntarily choose to expose herself to the dangers posed by using Yaz, Yasmin, and/or Ocella.

82. As a direct and proximate result of the Plaintiff's use of Yaz, Yasmin, and/or Ocella, she has incurred serious physical injuries and damages, including, but not limited to: mental pain and suffering, physical pain and suffering; and, medical and hospital expenses related to the treatment of her injuries and other damages.

COUNT II
PRODUCTS LIABILITY - INADEQUATE WARNINGS

83. Plaintiff incorporates by reference each preceeding and succeeding paragraph as though fully set forth herein.

84. Defendants manufactured, sold and distributed the Yaz, Yasmin, and Ocella without providing adequate warnings of the serious health risks associated with using the pills, including the possibility of pulmonary embolism, deep vein thrombosis, heart attack, stroke, cardiopulmonary arrest or death, which rendered the product unreasonably dangerous to the user or consumer.

85. At the time the product left the control of the Defendants, they knew or, in light of reasonably available knowledge, should have known about the danger that caused the harm suffered by the Plaintiff.

86. The product warning included in the Yaz, Yasmin, and Ocella packaging would not have been provided by a reasonably prudent person in the same or similar circumstances with respect to the danger. The product warning also insufficiently communicated information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to, a physician or other licensed professional who prescribes the drug.

87. The danger was not known or open and obvious to the user or consumer, including the Plaintiff or his health care providers, nor should it have been known or open and obvious, taking into account the characteristics of, and the ordinary knowledge common to, the persons who ordinarily use or consume the product.

88. Neither the Plaintiff nor her health care providers had knowledge that the Yaz, Yasmin, and Ocella was unsafe to her health and neither appreciated the danger posed by the defective condition of Yaz, Yasmin, and Ocella. Nor did the Plaintiff deliberately or voluntarily choose to expose herself to the dangers posed by using Yaz, Yasmin, and Ocella.

89. As a direct and proximate result of the Plaintiff's use of Yaz, Yasmin, and/or Ocella, she has incurred serious physical injuries and damages, including, but not limited to: mental pain and suffering, physical pain and suffering; and, medical and hospital expenses related to the treatment of her injuries and other damages.

COUNT III
PRODUCTS LIABILITY - BREACH OF EXPRESS WARRANTY

90. Plaintiff incorporates by reference each preceeding and succeeding paragraph as though fully set forth herein.

91. Defendants made an affirmation of fact or promise to the Plaintiff and her health care providers that Yaz, Yasmin, and Ocella was of merchantable quality and reasonably fit and safe for its intended and reasonably foreseeable use as a medication.

92. Defendants breached these warranties because the Yaz, Yasmin, and Ocella was not of merchantable quality, was not fit for its intended and reasonably foreseeable use, and was unreasonably dangerous in light of the risk of side effects associated with its use, including, but not limited to, pulmonary embolism, deep vein thrombosis, heart attack, stroke, or other adverse side effects to foreseeable users.

93. Plaintiff justifiably and detrimentally relied upon the warranties and representations of the Defendants in the purchase and use of Yaz, Yasmin, and Ocella.

94. As a direct and proximate result of the Defendants' breach of warranty, Plaintiff suffered serious physical injuries and damages.

COUNT IV
PRODUCTS LIABILITY - BREACH OF IMPLIED WARRANTY
OF FITNESS FOR PARTICULAR PURPOSE

95. Plaintiff incorporates by reference each preceeding and succeeding paragraph as though fully set forth herein.

96. At the time the Defendants manufactured, marketed, sold and distributed the Yaz, Yasmin, and Ocella, the Defendants knew that the purpose of the drug was to provide a reasonably safe oral contraceptive. The Defendants also knew that the Plaintiff, as a user and consumer, was relying on the Defendants' skill or judgment to furnish a safe medication for this particular use.

97. The Defendants impliedly warranted to the Plaintiff and her health care providers that the Yaz, Yasmin, and Ocella was of merchantable quality and reasonably fit and safe for its intended and reasonably foreseeable use as an oral contraceptive.

98. The Defendants breached this implied warranty because the Yaz, Yasmin, and Ocella was not fit for its intended and reasonably foreseeable use, and was unreasonably dangerous in light of the risk of defects, including, but not limited to, pulmonary embolism, deep vein thrombosis, heart attack, stroke, or other adverse side effects to foreseeable users.

99. Plaintiff justifiably and detrimentally relied upon the warranties and representations of the Defendants in the purchase and use of the Yaz, Yasmin, and Ocella.

100. As a direct and proximate result of the Defendants' breach of warranty, Plaintiff suffered serious physical injuries and damages.

COUNT V
NEGLIGENCE

101. Plaintiff incorporates by reference each preceeding and succeeding paragraph as though fully set forth herein.

102. Defendants had a duty to exercise reasonable care in the design, manufacture, marketing, sale, testing and/or distribution of the Yaz, Yasmin, and Ocella into the stream of commerce.

103. Defendants failed to exercise ordinary care in the design, manufacture, marketing, sale, testing and/or distribution of Yaz, Yasmin, and Ocella into the stream of commerce.

104. Defendants knew or reasonably should have known that the Yaz, Yasmin, and Ocella created an unreasonable risk of bodily harm or injury, including but not limited to, pulmonary embolism, deep vein thrombosis, heart attack, stroke, or other adverse side effects to those who would and did use the Yaz, Yasmin, and Ocella.

105. Despite the fact that the Defendants knew or reasonably should have known that Yaz, Yasmin, and Ocella created unreasonably dangerous side effects and risks, which many users would be unable to remedy by any means, Defendants continued to market the Yaz,

Yasmin, and Ocella to the consuming public, even though there were adequate and safer alternative methods of treatment or opportunities for more meaningful warnings.

106. As a direct and proximate result of the Plaintiff's use of Yaz, Yasmin, and/or Ocella, she has incurred serious physical injuries and damages, including, but not limited to: mental pain and suffering, physical pain and suffering; and, medical and hospital expenses related to the treatment of her injuries and other damages.

COUNT VI
FRAUDULENT INDUCEMENT AND SUPPRESSION

107. Plaintiff incorporates by reference each preceeding and succeeding paragraph as though fully set forth herein.

108. Defendants misrepresented to the Plaintiff and to the health care industry the safety and effectiveness of Yaz, Yasmin, and Ocella and/or fraudulently, intentionally and/or negligently concealed material information, including adverse information regarding the safety and effectiveness of Yaz, Yasmin, and Ocella.

109. Defendants made misrepresentations and actively concealed adverse information at a time when the Defendants knew, or should have known, that Yaz, Yasmin, and Ocella had defects, dangers, and characteristics that were other than what the Defendants had represented to the Plaintiff and the health care industry generally. Specifically, Defendants misrepresented to and/or actively concealed from the Plaintiff, the health care industry and consuming public that:

a) Yaz, Yasmin, and Ocella has statistically significant increases in cardiovascular side effects which could result in serious injury or death;
b) There had been insufficient and/or company-spun studies regarding the safety and efficacy of Yaz, Yasmin, and Ocella before and after the product launch;
c) Yaz, Yasmin, and Ocella was not fully and adequately tested for the cardiovascular side effects at issue herein;
d) Other testing and studies showed the risk of or actual serious adverse risks; and
e) There was a greatly increased risk of such cardiovascular events and death.

110. The misrepresentations of and/or active concealment alleged were perpetuated directly and/or indirectly by Defendants.

111. Defendants knew or should have known that these representations were false and made the representations with the intent or purpose that the Plaintiff would rely on them, leading to the use of Yaz, Yasmin, and Ocella.

112. At the time of Defendants' fraudulent misrepresentations, Plaintiff was unaware of the falsity of the statements being made and believed them to be true. Plaintiff had no knowledge of the information concealed and/or suppressed by Defendants.

113. Plaintiff justifiably relied on and/or was induced by the misrepresentations and/or active concealment and relied on the absence of safety information which the Defendants did suppress, conceal or failed to disclose to Plaintiff's detriment.

114. Defendants had a post-sale duty to warn Plaintiff and the public about the potential risks and complications associated with Yaz, Yasmin and Ocella in a timely manner.

115. The misrepresentations and active fraudulent concealment by the Defendants constitutes a continuing tort against the Plaintiff, who ingested Yaz, Yasmin, and/or Ocella.

116. Defendants made the misrepresentations and actively concealed information about the defects and dangers of Yaz, Yasmin, and Ocella with the intention and specific desire that Plaintiff's health care professionals and the consuming public would rely on such or the absence of information in selecting Yaz, Yasmin, and Ocella as treatment.

117. As a direct and proximate result of the fraudulent acts and omissions, suppression and misrepresentation of Defendants, Plaintiff suffered significant and ongoing injury and damages.

COUNT VII
COMMON LAW FRAUD

118. Plaintiff incorporates by reference each preceeding and succeeding paragraph as though fully set forth herein.

119. Defendants committed actual fraud by making material representations as stated herein which were false, knowing that such material representations were false and/or with reckless disregard for the truth or falsity of such material representations, with the intent that the Plaintiff relied on such material representations; Plaintiff acted in actual and justifiable reliance on such material representations and was injured as a result.

120. At the time they made these representations, Defendants knew or should have known that these representations were false.

121. These representations were made with the intent that those to whom they were directed would rely on them to their detriment; consequently, the Plaintiff and her physicians did in fact detrimentally rely on the misrepresentations.

122. As a direct and proximate result of the fraud by Defendants, Plaintiff suffered significant and ongoing injury and damages.

COUNT VIII
WANTONNESS

123. Plaintiff incorporates by reference each preceeding and succeeding paragraph as though fully set forth herein.

124. At all times relevant, the Defendants were under a duty to exercise reasonable care in the researching, manufacturing, selling, merchandising, advertising, promoting, labeling, analyzing, testing, distributing and marketing of Yaz, Yasmin, and Ocella for distribution, sale, and use by the general public, to ensure that Yaz, Yasmin, and Ocella's use did not result in avoidable injuries.

125. Plaintiffs injuries as described herein were caused by the wantonness of the Defendants through its agents, servants and/or employees acting within the course and scope of their employment, including among other things:

a) Carelessly and wantonly researching, manufacturing, selling, merchandising, advertising, promoting, labeling, analyzing, testing, distributing, and marketing Yaz, Yasmin, and Ocella;

b) Failing to fully disclose the results of the testing and other information in its possession regarding the association between Yaz, Yasmin, and Ocella and events such as stroke, heart attack, pulmonary embolism, deep vein thrombosis or other ischemic events;

c) Wantonly and carelessly failing to adequately warn the medical community and the general public, including the Plaintiff and her treating and prescribing medical provider(s), of the dangers of using Yaz, Yasmin, and Ocella;

d) Wantonly and carelessly describing and promoting Yaz, Yasmin, and Ocella as safe and effective;

e) Wantonly and carelessly failing to act as a reasonable prudent drug manufacturer; and

f) Wantonly and carelessly over-promoting and promoting Yaz, Yasmin, and Ocella in a zealous and unreasonable way, without regard to its potential dangers.

127. As a direct and proximate consequence of the wantonness and breach of Defendants, the Plaintiff sustained serious injuries. Defendants owed a duty to the Plaintiff to use reasonable care.

DEMAND FOR RELIEF

WHEREFORE, Plaintiff demands judgment against the Defendants for damages, as well as all costs of this action, to the full extent of the law, including:

a) Compensable Damages to compensate Plaintiff for serious injuries sustained as a result of the use of Yaz or Yasmin or Ocella;

b) Past and future lost income;

c) Past and future medical expenses;

d) Damages for the wanton, reckless, intentional and/or wrongful conduct of the Defendants and to punish and deter similar wrongful conduct;

e) Physical pain and suffering of Plaintiff;

f) Mental anguish and/or emotional distress;

g) Permanent injury;

h) Punitive damages; and

i) Any other applicable damages that the court finds appropriate.

JURY TRIAL DEMANDED

Plaintiff demands that all issues of fact in this case be tried by a properly impaneled jury.

Respectfully Submitted,

/s/ Joel L. DiLorenzo (ASB-7575-J64D)
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